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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,821	03/29/2001	Andrew A. Welcher	01017/36938A	6210

4743 7590 07/13/2004

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/821,821

Applicant(s)

WELCHER ET AL.

Examiner

Prema M Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8,10,51-55,70 and 72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-8, 10, 51-55, 70, 72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 4-8, 10, 51-55, 70, 72 are pending and under consideration.
2. Receipt of applicant's arguments and amendments filed 6/4/2004 is acknowledged.
3. Applicant's arguments filed on 6/4/2004 have been fully considered but were non-persuasive. The issues remaining are stated below.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections- 35 USC 101/112

5. Claims 1, 4-8, 10, 51-55, 70, 72 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

This rejection is maintained for reasons of record set forth at pages 5-7 of the previous Office action (10/15/02) and pages 3-9 of the previous Office action (12/4/03).

Applicants argue that the expression of the polynucleotides of the invention is greater in testis tissue than in other tissues (see Example 3, page 112). Furthermore, Applicants argue that the detection of metastasized cancer cells by specifically detecting cells of a given tissue type in atypical or abnormal in vivo locations was a utility well established in the art and the nucleic acid of the instant invention would be useful in a method for diagnosing metastasized testicular cancer cells. However, contrary to Applicants arguments, the instant utility for a method for diagnosing metastasized testicular cancer cells using the claimed nucleic acid was not presented in the disclosure as filed. Furthermore, there is no indication in the specification that overexpression of

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the nucleic acid in human testis cells provides a nexus to overexpression of the claimed nucleic acid in testicular cancer cells. Applicants have failed to demonstrate the overexpression of the instantly claimed nucleic acid in testicular cancer cells. Applicants have admitted on the record (page 5, third para, lines 4-5) that the application discloses that the gene corresponding to SEQ ID NO:1 has been shown to be expressed predominantly in testis tissue. However, there is no indication in the specification that the gene corresponding to SEQ ID NO:1 has been shown to be expressed predominantly in testicular cancer tissue.

Applicants argue that the Patent Office has not supported even a single example of a known protein specifically expressed in testis tissue. However, contrary to Applicants arguments, an example of a protein expressed only in testicular tissue is irrelevant here because the issue here is the utility of the claimed nucleic acid based on identification of testicular cancer cells. The point being made by the Examiner is that Applicants have failed to demonstrate that the nucleic acid of the instant invention is differentially expressed in testicular cancer cells.

Furthermore, Applicants argue that the claimed subject matter is supported by a patentable utility in the form of specifically detecting metastasized testicular cancer cells. However, contrary to Applicants' arguments, to demonstrate that the primary testicular cancer has metastasized, Applicants have to demonstrate that the secondary tumor was derived from the primary testicular cancer tumor cells. This could be done by showing that the genetic profile of the secondary tumor cells is identical to the primary testicular tumor cells. For example, the amount of mRNA obtained from transcription of the gene corresponding to SEQ ID NO: 1 should be the same in the primary tumor and in the

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secondary tumor if the secondary tumor is derived from the primary tumor i.e. the secondary tumor is a clone of the primary tumor. Therefore, the claimed invention is not supported by either a specific and substantially utility or a well established utility.

The declaration pursuant to 37 CFR 1.132 by Andrew Welcher on 10/14/2003 is acknowledged. The declaration is non-persuasive because it reiterates Applicants' arguments regarding the use of the claimed nucleic acid as a tissue-specific marker and as a chromosomal marker, which arguments have been addressed in the Office action filed on 12/4/2003.

Claims 1, 4-8, 10, 51-55, 70, 72 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification does not disclose any biological activity for the protein encoded by the claimed nucleic acid, nor does the instant specification disclose differential expression of the claimed nucleic acid in normal and testicular cancer cells, therefore, there is no specific and substantial asserted utility or well established utility for the claimed nucleic acid or the encoded protein. The fact that the claimed nucleic acid encodes a protein that has homology to human CD20/IgE-receptor is not sufficient to establish a specific and substantially asserted utility or a well established utility for it.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

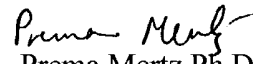
Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Prema Mertz Ph.D.
Primary Examiner
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June 21, 2004